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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/721,922 | 11/24/2003 | Markus Pompejus | BGI-132CPCN | 5830 |

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| EXAMINER | |
|---|---|
| ZARA, JANE J | |
| **ART UNIT** | **PAPER NUMBER** |
| 1635 | |

| SHORTENED STATUTORY PERIOD OF RESPONSE | MAIL DATE | DELIVERY MODE |
|---|---|---|
| 3 MONTHS | 03/22/2007 | PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/721,922 | POMPEJUS ET AL. | |
| | Examiner | Art Unit | |
| | Jane Zara | 1635 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *05 December 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *3,9-17,25,26 and 28-38* is/are pending in the application.

4a) Of the above claim(s) *35* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *3,9-17,25,26,28-34 and 36-38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

This Office action is in response to the communication filed 12-5-06.

### *Election/Restrictions*

Claims 18-24 and 35 withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 12-5-06.

Applicant's election without traverse of Group I, claims 1-17, 25-34 and 36-38 in the reply filed on 12-5-06 is acknowledged.

Claims 3, 9-17, 25, 26, 28-38 are pending in the instant application. Claims 1, 2, 4-8, 18-24, 27 have been cancelled by amendments filed 12-5-06. Claims 3, 9-17, 25, 26, 28-34 and 36-38 have been examined on their merits as set forth below. Claim 35 has been withdrawn, as being drawn to a non-elected invention.

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3, 9-17, 25, 26, 28-34 and 36-38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The metes and bounds of the invention cannot be determined because in claim 3, section f), it is unclear which fragment of at least 15 contiguous nucleotides of SEQ

ID NO. 3 encodes a polypeptide having a UDP-N-Acetylmuramate-Alanane-Ligase activity and in claim 38, it is unclear which region of SEQ ID NO. 1 constitutes the modified regulatory region and which region constitutes a wild-type regulatory region of the molecule. Appropriate clarification is required.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 3, 9-17, 25, 26, 28-34 and 36-38 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to compositions and methods comprising isolated nucleic acid molecules comprising any nucleic acid encoding a naturally occurring allelic variant of SEQ ID NO. 2, any isolated nucleic acid molecule comprising at least 90% identity with SEQ ID NO. 1, any fragment of at least 15 contiguous nucleotides of SEQ ID NO. 1 encoding polypeptide having a UDP-N-Acetylmuramate-Alanane-Ligase activity, and any region of SEQ ID NO. 1 constituting a modified regulatory region and in relation to the wild-type regulatory region of the molecule.

The specification, prior art and claims do not adequately describe the broad genera claimed. The specification and claims do not indicate what distinguishing

attributes are concisely shared by the members of the genera comprising allelic variants of SEQ ID NO. 2, homologues comprising at least 90% identity with SEQ ID NO. 1, fragments of at least 15 contiguous nucleotides of SEQ ID NO. 1 encoding a polypeptide having a UDP-N-Acetylmuramate-Alanane-Ligase activity, or any region of SEQ ID NO. 1 constituting a modified regulatory region in relation to the wild-type regulatory region of the molecule. Nor does the specification describe elements which are essential to various functions claimed for each genus. The specification does not place any limit on the number of nucleic acid or amino acid substitutions, deletions, insertions and/or additions that may be made within each genus claimed. The scope of the claims includes numerous structural variants, and each genus is highly variant because a significant number structural differences between genus members is permitted. Concise structural features that could distinguish compounds from others in each broad genus are missing from the disclosure. No common structural attributes identify members of the various, broadly claimed genera.

Furthermore, the specification fails to teach or adequately describe a representative number of species in each genus such that the common attributes or characteristics concisely identifying members of each proposed genus are exemplified. And the general knowledge and level of skill in the art do not supplement the omitted description because specific, not general, guidance is what is needed. Since the disclosure fails to describe the common attributes or characteristics concisely identifying members of the proposed genera, and because each genus is highly variant, the description provided for each genus is insufficient. One of skill in the art would

reasonably conclude that the disclosure fails to provide a representative number of species to describe the genera claimed. Thus, applicant was not possession of the claimed genera comprising allelic variants of SEQ ID NO. 2, homologues comprising at least 90% identity with SEQ ID NO. 1, fragments of at least 15 contiguous nucleotides of SEQ ID NO. 1 encoding a polypeptide having a UDP-N-Acetylmuramate-Alanane-Ligase activity, or any region of SEQ ID NO. 1 constituting a modified regulatory region in relation to the wild-type regulatory region of the molecule.

Claims 3, 9-17, 25, 26, 28-34 and 36-38 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for in vitro expression of SEQ ID No. 1 in an appropriate microbial host cell, does not reasonably provide enablement for compositions and methods for the production of fine chemicals from any naturally occurring allelic variant of SEQ ID NO. 2, any isolated nucleic acid molecule comprising at least 90% identity with SEQ ID NO. 1, any fragment of at least 15 contiguous nucleotides of SEQ ID NO. 1 encoding polypeptide having a UDP-N-Acetylmuramate-Alanane-Ligase activity, or any region of SEQ ID NO. 1 constituting a modified regulatory region and in relation to the wild-type regulatory region of the molecule. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claims are drawn to compositions and methods for the production or modulation of production of fine chemicals from any naturally occurring allelic variant of

SEQ ID NO. 2, any isolated nucleic acid molecule comprising at least 90% identity with SEQ ID NO. 1, any fragment of at least 15 contiguous nucleotides of SEQ ID NO. 1 encoding polypeptide having a UDP-N-Acetylmuramate-Alanane-Ligase activity, or any region of SEQ ID NO. 1 constituting a modified regulatory region and in relation to the wild-type regulatory region of the molecule. The following factors have been considered in determining that the specification does not enable the skilled artisan to make and/or use the invention over the scope claimed.

**The state of the prior art and the predictability or unpredictability of the art.** The determination of nucleic acid sequences derived from subcloning and sequencing of genomic *Corynebacterium glutamicum* from ATCC 13032 is not representative of the ability to produce fine chemicals, nor modulate the production of fine chemicals from any naturally occurring allelic variant of SEQ ID NO. 2, any isolated nucleic acid molecule comprising at least 90% identity with SEQ ID NO. 1, any fragment of at least 15 contiguous nucleotides of SEQ ID NO. 1 encoding polypeptide having a UDP-N-Acetylmuramate-Alanane-Ligase activity, or any region of SEQ ID NO. 1 constituting a modified regulatory region and in relation to the wild-type regulatory region of the molecule, nor is it representative of the ability to transfect SEQ ID NO. 1 into any host cell in an organism.

**The amount of direction or guidance presented in the specification AND the presence or absence of working examples**. Applicants have not provided guidance in the specification toward methods of producing fine chemicals from any isolated nucleic acids obtained from Corynebacterium glutamicum, including SEQ ID NO. 1, its

allelic variants or fragments, nor of determining any homologues or allelic variants of SEQ ID NO. 1, nor diagnosis of any infections in a subject, nor determining the regulatory regions that are modified relative to wild type regulatory regions of SEQ ID NO. 1, nor the transfection of host cells in a subject with the compositions claimed.

The instant specification teaches the sequencing of genomic *C. glutamicum* from ATCC 13032 using plasmids or cosmids in *E. coli*. One skilled in the art would not accept on its face the examples provided in the instant disclosure of the sequencing of genomic *C. glutamicum* from ATCC 13032 as being correlative or representative of producing fine chemicals or modulating the production of fine chemicals using the broad genus of compositions claimed in view of the lack of guidance in the specification and the known unpredictability associated with the ability to produce fine chemicals, express polypeptides, determine allelic variants and homologues, diagnose infections in an organism, or determine modified regulatory regions of such a broad array of sequences claimed.

**The breadth of the claims and the quantity of experimentation required.** The breadth of the claims is very broad. The claims are broadly drawn to compositions and methods for the production, or modulation of production of fine chemicals from any naturally occurring allelic variant of SEQ ID NO. 2, any isolated nucleic acid molecule comprising at least 90% identity with SEQ ID NO. 1, any fragment of at least 15 contiguous nucleotides of SEQ ID NO. 1 encoding polypeptide having a UDP-N-Acetylmuramate-Alanane-Ligase activity, or any region of SEQ ID NO. 1 constituting a

modified regulatory region and in relation to the wild-type regulatory region of the molecule.

The quantity of experimentation required to practice the invention as claimed would require the *de novo* determination of the ability to modulate production of fine chemicals using a representative number of species of each broadly claimed genus of compounds, whereby modulation of producing fine chemicals is obtained using any naturally occurring allelic variant of SEQ ID NO. 2, any isolated nucleic acid molecule comprising at least 90% identity with SEQ ID NO. 1, any fragment of at least 15 contiguous nucleotides of SEQ ID NO. 1 encoding polypeptide having a UDP-N-Acetylmuramate-Alanane-Ligase activity, and whereby any region of SEQ ID NO. 1 constituting a modified regulatory region and in relation to the wild-type regulatory region of the molecule has been determined.

Since the specification fails to provide any particular guidance for the successful production of any fine chemicals, or modulation of production of any fine chemicals using the nucleic acids encompassed by the broad genera claimed, and since determination of the factors required for accomplishing such production or modulated production is highly unpredictable, it would require undue experimentation to practice the invention over the broad scope claimed.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 3, 9-13, 15-17, 25 and 30-33 are rejected under 35 U.S.C. 102(b) as being anticipated by Smith et al (USPN 5,871,960).

Smith et al (USPN 5,871,960) teach isolated microbial host cells and expression vectors expressing nucleic acids encoding fragments of SEQ ID NO. 1 (see SEQ ID NO. 30 of Smith et al).

Claims 3, 9-13, 15-17, 25 and 30-33 are rejected under 35 U.S.C. 102(b) as being anticipated by Kobayashi et al (Accession No. AB003132, April 15, 1997).

Kobayashi et al (Accession No. AB003132) teach isolated microbial host cells and expression vectors expressing nucleic acids encoding fragments of SEQ ID NO. 1.

Claims 3, 9-13, 15-17, 25 and 30-33 are rejected under 35 U.S.C. 102(b) as being anticipated by Wachi et al (Accession No. AB015023, May 27, 1998).

Wachi et al (Accession No. AB015023, May 27, 1998) teach isolated microbial host cells and expression vectors expressing nucleic acids encoding fragments of SEQ ID NO. 1.

***Conclusion***

Certain papers related to this application may be submitted to Art Unit 1635 by facsimile transmission. The faxing of such papers must conform with the notices

published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. ' 1.6(d)). The official fax telephone number for the Group is 571-273-8300. NOTE: If Applicant does submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE CO PIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jane Zara whose telephone number is (571) 272-0765. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Douglas Schultz, can be reached on (571) 272-0763. Any inquiry regarding this application should be directed to the patent analyst, Katrina Turner, whose telephone number is (571) 272-0564. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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**3-17-07**

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